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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,628	06/22/2001	Vincent Chiang	15164.47	7405

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GRAY CARY WARE & FREIDENRICH LLP  
153 TOWNSEND  
SUITE 800  
SAN FRANCISCO, CA 94107

EXAMINER

SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 05/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/887,628**

Applicant(s)  
**Chiang**

Examiner  
**Sandra Saucier**

Art Unit  
**1651**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Mar 17, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above, claim(s) 21-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Jun 22, 2001 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2 6) ☐ Other:

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#### DETAILED ACTION

Claims 1-24 are pending. Claims 1-20 are considered on the merits. Claims 21-24 are withdrawn from consideration as being drawn to a non-elected invention.

#### *Election/Restriction*

Applicant's election of Group I in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

#### *Claim Rejections - 35 USC § 112* INDEFINITE

Claims 1-11, 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it recites "the quantity of  $\alpha$ -amylase formed". This is a misstatement of scientific fact.  $\alpha$ -amylase IS NOT FORMED, it is activated. Therefore, the assay is a measurement of the activity of  $\alpha$ -amylase. Also, the last line of claim 1 should state, "said activity of  $\alpha$ -amylase."

Claim 19 and 20 have no antecedent basis for the recitation of "said sodium ion compound".

#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12, 17 and 18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 99/50444 [N].

~~The claims are directed to a composition comprising:~~  
 $\alpha$ -amylase substantially  $\text{Ca}^{+2}$  free,  
 $\text{Na}^{+}$ ,  
substrate for detecting  $\alpha$ -amylase activity.

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The references are relied upon as explained below.

WO 99/50444 in example 1 discloses a composition comprising:  
 $\alpha$ -amylase substantially  $\text{Ca}^{+2}$  free (that is in the inactive form),  
 $\text{Na}^+$ ,  
substrate solution.

Claims 12-17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by JP 01-181799 [O].

JP 01-181799 discloses on page 5, lines 5-15 of the translation, a first composition comprising:

$\alpha$ -amylase substantially  $\text{Ca}^{+2}$  free (that is in the inactive form) page 2 of the translation,  
 $\text{Ca}^{2+}$  chelated with EDTA,  
EDTA,  
phosphate buffer brought to pH 7 with NaOH, (a source of sodium ions),

and a second composition comprising:

2-chloro-4-nitrophenyl- $\beta$ -D-maltoheptaoside.

The two reagents are combined in the performance of the assay.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 01-181799 [O].

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JP 01-181799 discloses a method of assaying  $\text{Cl}^-$  concentration comprising:

preparing a composition containing  $\alpha$ -amylase which is substantially  $\text{Ca}^{+2}$  free, that is, in the inactivated form, disodium EDTA, NaOH,  $\text{Ca}^{+2}\text{EDTA}$ ,

combining it with the  $\alpha$ -amylase activity detecting substrate which is in a 0.1M sodium phosphate buffer,

and the  $\text{Cl}^-$  sample and determining the  $\alpha$ -amylase activity which is correlated with  $\text{Cl}^-$  concentration.

The concentration of  $\text{Na}^+$  in the 0.1M sodium phosphate buffer at pH 7 is, at the very least, 0.1M, and the concentration of  $\text{Cl}^-$  in the sample, which is a NaCl solution, is at the very most 0.2M. Thus, the concentration of  $\text{Na}^+$  is clearly greater than the concentration of  $\text{Cl}^-$  as is required by the claim.

The  $\alpha$ -amylase has been rendered  $\text{Ca}^{2+}$  free by use of calcium ion chelating compounds such as EDTA (p. 4, l. 16).

The specific exemplified  $\alpha$ -amylase substrate is 2-chloro-4-nitrophenyl- $\beta$ -D maltoheptaoside, but any known substrate may be used (end of page 3 of the translation).

Chloride ion determinations may be performed in bodily fluids such as blood (page 6 of translation).

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP 01-181799 [O] and JP 11-266898 [P].

The claim is directed to the inclusion of 2-chloro-4-nitrophenyl- $\alpha$ -D-maltotrioside in the composition.

The references are relied upon as explained below.

JP 01-181799 on page 3 suggests that other compounds conventionally used may be substituted for the specifically listed  $\alpha$ -amylase substrates.

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JP 11-266898 teaches that 2-chloro-4-nitrophenyl- $\alpha$ -D-maltotrioside is a suitable compound for use in measuring  $\alpha$ -amylase activity.

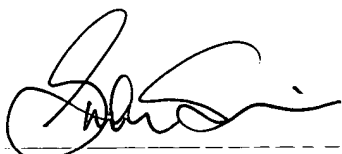
The substitution of 2-chloro-4-nitrophenyl- $\alpha$ -D-maltotrioside for 2-chloro-4-nitrophenyl- $\beta$ -D-maltoheptaoside in the composition of JP 01-181799 would have been obvious when the primary reference was taken with JP 11-266898 because JP 01-181799 suggests that any suitable substrate for the detection of  $\alpha$ -amylase activity may be used and JP 11-266898 demonstrates that 2-chloro-4-nitrophenyl- $\alpha$ -D-maltotrioside is such a suitable substrate.

One of ordinary skill in the art would have been motivated at the time of invention to make this substitution in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Claims 11, 19 and 20 appear to be free of the art.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.



Sandra Saucier  
Primary Examiner  
Art Unit 1651  
May 21, 2003